4. 510(k) Summary according to 807.92(c)

APR 2 8 2010

Contact: Jay Finster
R Tree Innovations, LLC
5956 Timber Ridge Drive
Suite 101
Prospect, KY 40059
502-689-4483

Trade Name: Epicage Interbody Fusion Device

Product Class: Class II

Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion device

Product Codes: MAX

Panel Code: 87

Indications for Use:
The Epicage Interbody Fusion Device is intended for interbody fusion procedures and is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental posterior fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Device Description:
The Epicage Interbody Fusion Device is a PEEK implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is designed with openings for bone growth and fusion. The rib allow for flexure of the device during insertion.

The device is available in two lengths to accommodate various patients' anatomy. Each of these sizes is available in 4 heights ranging from 8mm to 14mm in 2mm increments.

Predicate Device(s):
The Epicage Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the BAK Interbody Fusion Device (Spine-Tech, P950002), the Ray Threaded Fusion Cage (P950019), the Brantigan Lumbar I/F Cage (P960025) and the ROI-T device from LDR (K082262)

Performance Testing:
Static axial compression, static compression shear, static torsion, dynamic axial compression and dynamic torsion were completed following ASTM F2077-03. Subsidence was tested following ASTM F2267-04. Expulsion testing was conducted following a recognized protocol to allow comparison evaluation of intervertebral body fusion device assemblies, and characterize their resistance to expulsion. The above pre-clinical testing performed on the Epicage Interbody Fusion Device indicated that the Epicage Interbody Fusion Device is substantially equivalent to the predicate devices and is adequate for the intended use.

Summary:
The Epicage Interbody Fusion Device and predicate devices have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Epicage Interbody Fusion Device contain no new language that is not already included in at least one of the predicate devices. Moreover, the device is very similar in its size to the predicate devices. The materials used are also the same as in some predicate devices. There are no significant differences in technological characteristics compared to the predicates, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance, as discussed below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 28 2010

R Tree Innovations, LLC
% Dr. Richard Jansen
Silver Pine Consulting
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K092901
Trade/Device Name: Epicage Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 17, 2010
Received: April 20, 2010

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement of Indications for Use

510(k) Number (if known): K092901

Indications for Use:

The Epicage Interbody Fusion Device is intended for interbody fusion procedures and is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental posterior fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092901

Concurrence of CDRH, Office of Device Evaluation (ODE)